IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GIANNA KRSTIC, Plaintiff, v. SOFREGEN MEDICAL, INC., and ALLERGAN, INC., Defendants.	Civil Action No. 1:18-cv-11585-NMG **ORAL ARGUMENT REQUESTED**

MEMORANDUM IN SUPPORT OF THE MOTION TO DISMISS OF DEFENDANT SOFREGEN MEDICAL, INC.

Ellen Epstein Cohen (BBO# 543136)
ecohen@adlercohen.com
Ian Keefe (BBO# 680156)
ikeefe@adlercohen.com
Shea A. Miller (BBO# 699326)
smiller@adlercohen.com
Adler | Cohen | Harvey | Wakeman | Guekguezian, LLP
75 Federal Street, 10th Floor
Boston, MA 02110
(617) 423-6674

Attorneys for Defendant Sofregen Medical, Inc.

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PRELIMINARY STATEMENT

Defendant Sofregen Medical, Inc. ("Sofregen"), by and through its attorneys, Adler Cohen Harvey Wakeman Guekguezian, LLP, moves to dismiss all claims against it in their entirety pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. This case concerns the SERI® Surgical Scaffold ("SERI®"), an FDA-approved surgical scaffold for use in plastic surgery and reconstructive surgery. Plaintiff Gianna Krstic, a Florida resident at the time of her alleged injury, instituted this product liability action arising out of the use of SERI® in a total breast augmentation surgery she underwent on July 16, 2014. Plaintiff alleges that, at the time of her surgery and at the time of a subsequent corrective surgery on September 29, 2015, Defendant Allergan, Inc. ("Allergan") manufactured, distributed, sold, and marketed SERI®.

Sofregen has always been a separate and distinct corporate entity from Allergan. Sofregen's only association with SERI® is that on or about November 14, 2016, Sofregen acquired SERI® from Allergan. None of the allegations as to Sofregen concern any direct participation in the averred torts, other than the fact that Sofregen purchased SERI® over one year after the surgeries at issue. Thus, because the liabilities of the selling predecessor corporation Allergan regarding SERI® are not imposed upon the purchasing successor corporation Sofregen, Plaintiff fails to state a claim upon which relief can be granted. Although certain exceptions to this general rule exist, Plaintiff failed to assert the applicability of any exception.

Plaintiff's claims also fail on other grounds. First, Plaintiff's Amended Complaint fails to satisfy minimum pleading standards. Second, nearly all of Plaintiff's claims are preempted. Third, Massachusetts consumer protection laws are inapplicable to transactions consummated

outside of Massachusetts. For these reasons, as more particularly described below, this Court should grant Sofregen's motion and dismiss this lawsuit in its entirety.

FACTUAL BACKGROUND AND SUMMARY OF ALLEGATIONS

A. SERI® Surgical Scaffold

SERI® is a "knitted, multifilament, bioengineered, long-term bioresorbable scaffold… derived from silk." *Amended Complaint*, ¶ 32. "SERI® is designed to slowly bioresorb in parallel neovascularization and native tissue ingrowth which results in eventual replacement of SERI® with native tissue." *Id.* In 2008, the United States Food and Drug Administration ("FDA") cleared SERI® as a substantially equivalent product under Section 510(k) of the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). *Id.*, ¶ 44. In 2010, Allergan acquired SERI®. *See id.*, ¶ 31. "At all relevant times hereto, the Allergan Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, [and] marketing [of SERI®]…." *Id.*, ¶ 14.

B. Plaintiff's Surgeries

Plaintiff alleges that on or about July 16, 2014, Deirdre M. Marshall, M.D. performed a total breast augmentation surgical procedure on Plaintiff at South Miami Hospital in Miami, Florida. *Id.*, ¶ 19. During the reconstructive surgery, Dr. Marshall bilaterally implanted SERI® in Plaintiff's breasts. *See id.*, ¶ 2. As alleged, Plaintiff experienced right arm pain and immobilization sometime after the implantation surgery. *See id.*, ¶ 20. Plaintiff avers that her injuries were caused by the implanted SERI® failing to biodegrade in her right side resulting in a related infection. *See id.*, ¶ 23. On September 29, 2015, Plaintiff underwent a surgical procedure to remove the previously implanted breast capsule and SERI®. *See id.*, ¶¶ 23-24. Following the September 29, 2015 surgery, Plaintiff received further treatment to address complications

associated with SERI®. *See id.*, ¶ 26. As a result of the implantation of SERI® from 2014 to 2015, Plaintiff asserts that she "has suffered and continues to suffer from anxiety and depression, pain and has suffered, and will continue to suffer, a substantial wage loss." *Id.*, ¶ 27.

C. Sofregen's Acquisition of SERI®

Sofregen is a privately held Delaware corporation with its principle place of business in Massachusetts. *Id.*, ¶¶ 9, 11. Allergan is a Delaware corporation with its principle place of business in California. *See id.*, *preamble*. Both Sofregen and Allergan currently exist as separate and distinct corporate entities. *Id.* On or about November 14, 2016, Sofregen purchased SERI® from Allergan. *See id.*, ¶¶ 9, 34. Plaintiff does not allege that Sofregen manufactured, distributed, sold, and/or marketed the specific SERI® product used in Plaintiff's total breast augmentation surgery. Plaintiff does not allege that Sofregen manufactured, distributed, sold, and/or marketed SERI® at all prior to November 14, 2016. *See id.*, ¶ 14. Rather, Plaintiff's assertion of liability rests on the legal conclusion that Sofregen is Allergan's "successor in interest" regarding SERI®. *See id.*, ¶¶ 48-51.

ARGUMENT

I. LEGAL STANDARD

To survive a motion to dismiss, Plaintiff's Amended Complaint must set forth a "plausible entitlement to relief." *See Bell. Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). "[I]n order to 'show' an entitlement to relief[,] a complaint must contain enough factual material 'to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Ocasio-Hernãndez v. Fortuño-Burset*, 640 F.3d 1, 12 (1st Cir. 2011) (citing *Twombly*, 550 U.S. at 557). Dismissal is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element

necessary to sustain recovery under some actionable legal theory." *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (quoting *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005)). Although all well-pleaded facts must be taken as true, "[the Court] need not credit 'bald assertions, periphrastic circumlocutions, unsubstantiated conclusions, or outright vituperation,' or 'subjective characterizations, optimistic predictions, or problematic suppositions.'" *Id.* Rather, in assessing the plausibility of Plaintiff's claims, this Court must "identify[] and disregard[] statements in the complaint that merely offer 'legal conclusion[s] couched as … fact[]' or '[t]hreadbare recitals of the elements of a cause of action.'" *Ocasio-Hernãndez*, 640 F.3d at 12.

Here, Plaintiff's assertion that Sofregen is Allergan's "successor in interest" is a bald legal conclusion devoid of factual support. Thus, Plaintiff fails to state a claim upon which relief can be granted. Independent of Sofregen's corporate successorship immunity, Plaintiff's claims fail on other grounds and must therefore be dismissed.

II. CHOICE-OF-LAW ANALYSIS

Where federal jurisdiction is based on diversity of citizenship, "a federal court must draw the substantive rules of decision, including conflict of law principles, from the law of the forum state." *Butler v. Balolia*, 736 F.3d 609, 612 (1st Cir. 2013). Sofregen maintains that Florida law applies to Plaintiff's substantive claims and Delaware law to Sofregen's corporate successorship immunity. Under such a choice-of-law analysis, Plaintiff fails to state a claim upon which relief can be granted.

A. Florida Law Applies to Plaintiff's Substantive Claims

Under Massachusetts choice-of-law rules, Florida law applies to Plaintiff's substantive claims. A Federal Court exercising diversity jurisdiction applies the choice-of-law analysis of the

forum state – here, Massachusetts. *See Reicher v. Berkshire Life Ins. Co. of Am.*, 360 F.3d 1, 4-5 (1st Cir. 2004). Where Plaintiff alleges tort liability, the Restatement (Second) of Conflict of Laws ("Restatement") provides that the rights and liabilities of the parties are determined by the state which has 'the most significant relationship' to the underlying events and parties, taking into account: "(a) the place where the injury occurred, (b) the place where the conduct causing injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." *Burleigh v. Alfa Laval, Inc.*, 313 F. Supp. 3d 343, 352 (D. Mass 2018); *accord Cosme v. Whitin Mach. Works, Inc.*, 417 Mass. 643, 646 n.3 (1994). More specifically, several cases in this Circuit have also recognized that, under the Massachusetts choice-of-law rules, "tort claims are governed by the law of the state where the alleged injury occurred, unless another state has a more significant relationship to the cause of action." *Dunfey v. Roger Williams Univ.*, 824 F. Supp. 18, 21 (D. Mass. 1993); *accord Asymmetrx Med., Inc. v. McKeon*, 932 F. Supp. 2d 232, 238 (D. Mass. 2013). The place where the injury occurred "is the place where the last event necessary to make an actor liable for an alleged tort takes place." *Asymmetrx*, 932 F. Supp. 2d at 238 (quoting *Dunfey*, 824 F. Supp. at 21).

Under the relevant factors, Florida, where Plaintiff's alleged injuries occurred, has the most significant relationship to the underlying events. At all relevant times, Plaintiff resided in Florida. *See Am. Compl.*, ¶ 10. Plaintiff's staged bilateral breast reconstruction and implant exchange occurred in Florida by a Florida-based physician. *See id.*, ¶ 2. Further, the specific SERI® at issue was sold in Florida to a Florida-based physician, Florida-based practice group, or a Florida hospital. *See id.*, ¶ 14. Following her total breast augmentation surgery, Plaintiff sought additional treatment from a Florida-based physician and suffered her alleged injuries in Florida.

See id., ¶ 41. Under these alleged facts, Florida has the most significant relationship to the tort claims pled and, therefore Florida law must apply to Plaintiff's substantive claims. *See, e.g.*, *Asymmetrx*, 932 F. Supp. 2d at 239 (holding that Connecticut law applied to counterclaims, because alleged injury occurred in Connecticut, even though defendants-in-counterclaim, and the corporate entity at issue, were located in Massachusetts).

B. Delaware Law Applies to Sofregen's Corporate Successorship Immunity

Under Massachusetts choice-of-law principles, a Federal Court sitting in diversity "should weigh the relevant considerations 'according to their relative importance to the particular issue involved.'" *Robidoux v. Muholland*, 642 F.3d 20, 25 (1st Cir. 2011) (quoting *Lou v. Otis Elevator Co.*, 77 Mass. App. Ct. 571, 586 (2010)). Accordingly, "different laws could apply to different aspects of a case, depending on which state has the dominant interest in their resolution." *Reisch v. McGuigan*, 745 F. Supp. 56, 59 (D. Mass. 1990). After weighing the relevant considerations, Delaware law applies to Sofregen's corporate law immunity from Plaintiff's claims.

Here, the determination of Sofregen's corporate successorship immunity is a matter separate from Plaintiff's product liability claims. Indeed, "which state's corporate successorship law applies… is a distinct question from which state's product liability law applies." *Chubb Nat'l Ins. Co. v. Watts Regulator Co.*, 258 F. Supp. 3d 212, 216 (D. Mass. 2017). Thus, the choice-of-law analysis must also be distinct. *See Carriero v. Rhodes Gill & Co.*, No. 91-cv-10515 (RGS), 1995 WL 866092, at *2 (D. Mass. Jan. 13, 1995) ("[Plaintiff] argues that Massachusetts has the greater interest in the proceeding because the accident occurred in Massachusetts. This, however, is beside the point because the controversy to be decided involves [successor corporation's] corporate identity and not the ultimate issue of product liability.")

For questions of corporate law, Massachusetts courts follow the general choice-of-law rule, codified in Section 302 of the Restatement, that "the law of the state of incorporation applies in matters relating to the internal affairs of a corporation." *Harrison v. NetCentric Corp.*, 433 Mass. 465, 470-71 (2001) (citing Restatement (Second) of Conflict of Laws § 302); *accord Micro Networks Corp. v. HIG Hightec, Inc.*, 195 F. Supp. 2d 255, 265 n.1 (D. Mass. 2001). "This rule furthers the interests of 'certainty, predictability and uniformity of result, ease in the application of the law to be applied and, at least on occasion, protection of the justified expectations of the parties.'" *Harrison*, 433 Mass. at 472 (quoting Restatement (Second) of Conflict of Laws § 302, comment g). Here, any liability attributed to Sofregen would be based on theories of corporate agreement, *de facto* merger, mere continuation, or corporate fraud, not the underlying tort. In short, because the issue of whether the SERI® asset transfer triggered an exception to corporate successorship immunity is peculiar to corporations, Delaware law must apply unless another state has a more significant interest.[1] *See Carriero*, 1995 WL 866092, at *2.

Thus, where both Sofregen and Allergan are Delaware corporations, Delaware has the most significant interest in resolving this issue of corporate law. *See Am. Compl.*, ¶¶ *preamble*, 9, 11. Both defendants incorporated under Delaware law and expected to resolve issues of corporate governance under that state's law. Conversely, any interest of Plaintiff's home state of North Carolina is diminished when all relevant conduct occurred in Florida. *See id.*, ¶ 10. Likewise, Florida's interest is diminished when there is no allegation that the corporate transaction occurred within its borders and Plaintiff no longer resides there. *See id.*, ¶ 10. In sum, because Delaware has the most significant interest in the issue of corporate successorship,

[1] This rule is consistent with the Restatement's view of other corporate immunity defenses. *See* Restatement (Second) of Conflict of Laws § 145, comment d ("charitable immunity may be determined by the local law of the state where the plaintiff is domiciled and the defendant incorporated rather than by the local law of the state where conduct and injury occurred.").

Delaware law applies. However, as all potential jurisdictions abide by the same general corporate successorship immunity rule, Sofregen is not liable for Plaintiff's claims under any choice-of-law analysis. *See, e.g., Bernard v. Key Manufacturing Co., Inc.*, 409 So. 2d 1047, 1049-50 (Fla. 1982); *Cargill, Inc. v. Beaver Coal & Oil Co., Inc.*, 424 Mass. 356, 359 (1997); *Becker v. Graber Builders, Inc.*, 561 S.E.2d 905, 909 (N.C. App. 2002).

III. SOFREGEN IS NOT LIABLE FOR ANY ALLEGED TORTIOUS CONDUCT OF ALLERGAN THAT OCCURRED PRIOR TO SERI® ACQUISITION

Plaintiff's claims arise exclusively out of alleged negligence and strict liability pertaining to the manufacture, design, distribution, marketing, sale, and/or warranty of SERI® prior to the September 29, 2015 surgery. *See Am. Compl.*, ¶ 14. To plausibly allege each element of her claims, Plaintiff needed to assert facts showing that a defendant owed her a duty of care or was in privity to an express or implied warranty. *See Cooper v. Old Williamsburg Candle Corp.*, 653 F. Supp. 2d 1220, 1225-26 (M.D. Fla. 2009).

Here, Plaintiff does not allege any factual basis to establish the necessary elements of causation or relationship for her direct claims against Sofregen. Even assuming all allegations as true, Allergan was the only identified defendant with any connection to Plaintiff during all times relevant to her claims. *See Am. Compl.*, ¶¶ 14, 34. Recognizing this deficiency, Plaintiff relies on the mere unsubstantiated legal conclusion that Sofregen is Allergan's "successor in interest" as an attempt to extend the liability for her underlying cause of action. *See id.*, ¶¶ 48-51. However, under Delaware law, a corporation that merely purchases the assets of another corporation "is not liable for the seller's debts and liabilities of the transferrer, including those arising out of the former's tortious conduct." *Fehl v. S.W.C. Corp.*, 433 F. Supp. 939, 945 (D. Del. 1977); *accord Fountain v. Colonial Chevrolet Co.*, No. 85C-DE-88 (VAB), 1988 WL 40019, at *7 (Del. Super.

Ct. Apr. 13, 1988). Delaware does recognize four common-law exceptions to this general rule, when:

> "(1) the purchaser expressly or impliedly assumes such obligations; (2) the transaction amounts to a consolidation or merger of the seller into the purchaser; (3) the purchaser is merely a continuation of the seller; or (4) the transaction has been entered fraudulently."

Elmer v. Tenneco Resins, Inc., 698 F. Supp. 535, 540 (D. Del. 1988); *see also Knapp v. North American Rockwell Corp.*, 506 F.2d 361, 363-64 (3d Cir. 1974).

Nevertheless, the common-law exceptions do not apply and therefore Plaintiff cannot demonstrate an entitlement to relief under a theory of successor liability. Accordingly, Plaintiff's claims against Sofregen must be dismissed.

A. No Express or Implied Assumption of Allergan's Obligations

In order to satisfy the first exception to corporate successorship immunity, Plaintiff needed to allege that Sofregen expressly or implicitly assumed the obligations of Allergan. Plaintiff failed to aver facts that could plausibly suggest any such agreement. Regarding Sofregen's SERI® asset acquisition, Plaintiff's allegations are merely that on or about November 14, 2016, Sofregen purchased SERI® from Allergan. *See Am. Compl.*, ¶ 9, 34. With no further factual allegations, the Court cannot make the far-reaching inference that Sofregen assumed *any* liability for Plaintiff's injuries. *See Twombly*, 550 U.S. at 555; *see also Magnolia's at Bethany, LLC v. Artesian Consulting Engineers, Inc.*, No. S11 C-04-013 (ESB), 2011 WL 4826106, at *2 (Del. Super. Ct. Sept. 19, 2011).

B. The Asset Purchase of SERI® was not a *De Facto* Merger

Plaintiff does not allege facts demonstrating that the November 14, 2016 SERI® asset purchase constituted a *de facto* merger and, therefore, Plaintiff cannot establish the second exception to the general rule against successor liability. Under Delaware law, a *de facto* merger

requires that: "(1) one corporation has transferred all of its assets to another corporation; (2) payment was made in stock, issued by the transferee directly to the shareholders of the transferor corporation; and (3) in exchange for their stock, the transferee agreed to assume all the debts and liabilities of the transferor." *Marnavi S.p.A. v. Keehan*, 900 F. Supp. 2d 377, 397 (D. Del. 2012) (quoting *Xperex Corp. v. Viasystems Tech. Corp., LLC*, No. 20582-NC, 2004 WL 3053649, *2 (Del. Ch. July 22, 2004)). Here, Plaintiff does not allege any transfer of assets beyond SERI® and she does not allege that the purchase was made in stock. *See Am. Compl.*, ¶¶ 9, 34. Plaintiff's Amended Complaint even states that both corporate entities continued to exist subsequent to the purchase and sale of SERI® and still exist to this day. *See id.*, ¶¶ *preamble*, 11, 32 n.1. Indeed, there can be no *de facto* merger where, as here, both corporations continue to exist as separate entities. *See, e.g.*, *Marnavi*, 900 F. Supp. 2d at 397 (holding that the continuation of at least one product line was immaterial where the old company and new company "co-existed" for three years). Accordingly, Plaintiff cannot demonstrate that the SERI® sale and purchase constituted a *de facto* merger.

C. Sofregen is not a Mere Continuation of Allergan

For the same reasons, Plaintiff does not establish the existence of the third exception – that Sofregen is a "mere continuation" of Allergan. Significantly, the mere continuation theory of successor liability "has been narrowly construed by the Delaware courts." *Magnolia's at Bethany*, 2011 WL 4826106, at *3; *accord Marnavi*, 900 F. Supp. 2d at 397. The exception applies only if the purchaser is the "same legal person [as the former corporation], having a continued existence under a new name." *Elmer*, 698 F. Supp. at 542 (quoting *Fountain v. Colonial Chevrolet Co.*, 1988 WL 40019, at *9 (Del. Super. Ct. Apr. 13, 1988)). Notably, "[t]he test is not the continuation of the business operation." *Id.* Nor is it the continuation of the old

entity's product lines. *See Marnavi*, 900 F. Supp. 2d at 397. Indeed, "[i]mposition of successor liability is only appropriate where the new entity is so dominated and controlled by the old company that separate existence must be disregarded." *AJZN, Inc. v. Yu*, No. 13-cv-149 (GMS), 2015 WL 331937, at *15 (D. Del. Jan. 26, 2015) (internal quotation marks omitted; *see also Magnolia's at Bethany*, 2011 WL 4826106, at *3 ("The primary elements of continuation include the common identity of the officers, directors, or stockholders of the predecessor and successor corporations, and the existence of only one corporation at the completion of the transfer.").

As previously noted, Plaintiff does not aver any continuity of shareholders in this matter. Nor could Plaintiff plausibly do so – Sofregen and Allergan are separate entities with no alleged common ownership or managerial control. *See Am. Compl.*, ¶¶ *preamble*, 11. Moreover, there is no allegation that Allergan transferred any stock to Sofregen at the time of SERI® sale. Accordingly, Plaintiff's Amended Complaint does not plausibly allege that Sofregen is a "mere continuation" of Allergan.

D. <u>No Fraudulent Transfer</u>

Plaintiff's Amended Complaint lacks any allegations of fraud. To support a claim for fraudulent transfer, Plaintiff, at this stage in the litigation, must allege facts from which the Court may draw a reasonable inference that the transfer was made "(1) [w]ith actual intent to hinder, delay or defraud any creditor of the debtor; or (2) [w]ithout receiving a reasonably equivalent value in exchange for the transfer or obligation, and the debtor" either "(a) was insolvent or became insolvent as a result of the transfer, (b) engaged in or was about to engage in a transaction with respect to which its remaining assets would be unreasonably small; or (c) intended to incur or reasonably should have believed it would incur debts beyond its ability to

pay." 6 *Del. C.* § 1304; *Seiden v. Kaneko*, No. 9861 (VCN), 2015 WL 7289338, at *13 (Del. Ch. Nov. 3, 2015); *see also In re Plassein Int'l Corp.*, 428 B.R. 64, 67 (D. Del. 2010). Here, Plaintiff simply did not plead any facts to support an inference that the fraudulent transaction exception applies.

Because the only relationship between Allergan and Sofregen is the asset purchase of SERI®, it was incumbent upon Plaintiff to overcome the default rule of corporate successorship immunity by plausibly alleging that one or more of the four exceptions are met. The Amended Complaint is devoid of any such allegations. As such, there is no support for the bald legal conclusion that Sofregen is Allergan's successor in interest. Therefore, Plaintiff's claims against Sofregen must be dismissed.

IV. PLAINTIFF FAILS TO STATE CLAIMS UNDER FLORIDA LAW

Federal Courts applying Florida law routinely dismiss complaints in products liability actions that contain nothing more than speculation, conclusory statements and threadbare recitals of the elements of causes of actions.[2] *See, e.g.*, *Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159 (S.D. Fla. 2009). Consistent with this authority, *Counts II*, *III*, and *IV* of Plaintiff's Amended Complaint do not satisfy the *Twombly-Iqbal* pleading requirements. Accordingly, these claims must be dismissed independent of Sofregen's corporate successorship immunity.

A. <u>Plaintiff Fails to State a Claim for Breach of Warranty</u>

Florida law is clear: privity is required in order to recover damages from the seller of a product for breach of express or implied warranties. *Jovine v. Abbott Laboratories, Inc.*, 795 F. Supp. 2d 1331, 1340 (S.D. Fla. 2013); *Fields v. Mylan Pharm., Inc.*, 751 F. Supp. 2d 1257, 1259 (N.D. Fla. 2009); *accord Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37, 39 (Fla. 1988). "A

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[2] Plaintiff incorrectly alleges claims based on Massachusetts law. *See Am. Compl.*, ¶¶ 86-104. As noted above, Florida law applies to Plaintiff's substantive claims.

plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant." *T.W.M. v. American Medical Systems, Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) (holding that plaintiff failed to state a cause of action for breach of express or implied warranties because the complaint did not allege that the plaintiff purchased the medical device at issue "directly from the defendant, or that they contracted with the defendant."). Here, Plaintiff's Amended Complaint is similarly lacking. As alleged, Sofregen or Allergan did not sell SERI® to Plaintiff, but instead to "[Dr. Marshall], her practice group, or to South Miami Hospital." *See Am. Compl.*, ¶ 14. Consequently, Plaintiff's Amended Complaint cannot sustain claims of breach of warranty.[3]

B. <u>Plaintiff's Claim of Fraud Fails to Satisfy Federal Rule 9(b)</u>

Regardless of whether Plaintiff articulates *Count III* of her Amended Complaint as fraudulent misrepresentation or fraudulent concealment, such a theory of liability is subject to the heightened particularity standard of Federal Rule 9(b) and is insufficiently plead. *See Presto v. Sequoia Systems, Inc.*, 633 F. Supp. 1117, 1119 (D. Mass. 1986). Claims subject to Federal Rule 9(b), must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To satisfy the heightened pleading standard Plaintiff needed to aver "the who, what, where, and when of the allegedly false or fraudulent representation.'" *Rodi v. Southern New England School of Law*, 389 F.3d 5, 15 (1st Cir. 2004) (quoting *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)). Here, the Amended Complaint is devoid of specific facts regarding the who, what, where, and when of any alleged fraudulent action that allegedly took

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[3] Any claim of breach of warranty is independently lacking because Plaintiff failed to provide notice as required under Florida law. *See Jovine*, 795 F. Supp. 2d at 1339-40.

place.[4] Because Plaintiff fails to satisfy Federal Rule 9(b)'s heightened pleading requirements, her claim sounding in fraud must be dismissed.

V. PLAINTIFF'S CLAIMS ARE PREEMPTED

Plaintiff's Amended Complaint is laced with allegations that Allergan promoted SERI® for "off-label" uses—*i.e.*, uses not approved by FDA-mandated label. *See Am. Compl.*, ¶¶ 58-71. But those allegations do not alter the fact that Plaintiff's state-law claims are preempted because they would impose requirements different from or in addition to those imposed by the FDA. *See Byrnes v. Small*, 60 F. Supp. 3d 1289, 1297 (M.D. Fla. 2015) ("[T]o the extent that the claim is based on [defendant's] failure to warn the medical community of the dangers associated with the off-label use of [medical device], including any purported inadequacies in the warnings and labels accompanying [medical device], it is expressly preempted."). Moreover, even if Plaintiff's claims are not expressly preempted, any cause of action seeking to enforce the FDCA provisions that purportedly govern the off-label promotion of medical devices or manufacturers' communications with the FDA, are impliedly preempted under 21 U.S.C. § 337(a)), which directs that all actions to enforce the FDCA "shall be by and in the name of the United States" and thus forbids private actions to enforce the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

"[T]here is no claim for illegal off-label promotion rooted in traditional state tort law." *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1070 (W.D. Mo. 2014) (quoting *Dunbar v.*

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[4] Plaintiff's fraud claim appears to be based on an alleged scheme to conceal or misrepresent alleged material information from the medical community. *See Am. Compl.*, ¶¶ 118-124. Although Plaintiff alleges generally that Sofregen and Allergan promoted off-label use of SERI®, that is irrelevant because "off-label marketing ... is itself not inherently fraudulent." *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 n.6, 1054 (N.D. Cal. 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011). Rather, to sustain her claim, Plaintiff must identify a particular misrepresentation (attributable to Sofregen or Allergan) on which Plaintiff, or Plaintiff's physicians, reasonably relied. *See, e.g., Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1180 (C.D. Cal. 2013). Here, because "[c]onclusory allegations and references to 'plans and schemes' are not sufficient[]", Plaintiff's unsubstantiated claim based on fraud must be dismissed. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007).

Medtronic, Inc., No. CV 14-01529 (RGK) (AJWx), 2014 WL 3056026 (C.D. Cal. June 25, 2014)). Indeed, the very concept of off-label promotion did not exist—and could not exist—until Congress enacted the MDA and required that manufacturers obtain FDA approval of devices and their labels. *See Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219–20, 1224 (W.D. Okla. 2013) ("[T]he concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] law."). Thus, the distinction between on-label and off-label use—and, hence, between on-label and off-label promotion—exists only by virtue of the federal regulatory scheme. *See id.* Claims predicated on off-label promotion are thus impliedly preempted under *Buckman* and § 337(a), "because promoting the off-label use of an FDA-approved medical device is not unlawful under 'traditional state tort law'" and any claim based on off-label promotion "would be in substance a claim for violating the FDCA." *Dawson v. Medtronic, Inc.*, No. 3:13-cv-663 (JFA), 2013 WL 4048850, at *6 (D.S.C. Mar. 25, 2014) (quoting *Buckman*, 531 U.S. at 353); *see also, e.g.*, *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119 (9th Cir. 2013). Ultimately, Plaintiff's claims based on alleged off-label promotion are simply an attempt by a private party to enforce the MDA and are therefore foreclosed by § 337(a) as construed in *Buckman*. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 790 (3d Cir. 1999) (claim that assigns a state-law moniker to the enforcement of a federal regulation is preempted). Thus, Plaintiff's claims based on off-label promotion must be dismissed.

VI. PLAINTIFF'S CLAIM UNDER MASS. GEN. LAWS. CH. 93A FAILS

Massachusetts consumer protection laws cannot apply to Plaintiff's claim regarding a sale consummated outside of Massachusetts. *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 65 F. Supp. 3d 283, 295 (D. Mass. 2014) ("Massachusetts choice-of-law rules, which govern in this case because the complaint was filed in the District of Massachusetts,"

mandate that "class members' consumer protection claims are governed by the laws of their home states."); *So. States Police Benevolent Ass'n v. First Choice Armor & Equip., Inc.*, 241 F.R.D. 85, 93 (D. Mass. 2007) ("[B]ecause state consumer protection laws are intended to protect consumers, the Court concludes that the laws of the home states will govern here."). Other courts applying similar tests regarding consumer protection statutes have reached the same conclusion. *See, e.g.*, *In re Intel Corp. Microprocessor Antitrust Litig.*, No. 05-485, 2010 WL 8591815, at *54 (D. Del. July 28, 2010) ("It is hard to see why the laws of other states should be tossed overboard and their residents remitted to [a single state's] law for transactions that, for individual consumers, are local in nature."); *see also In re Relafen Antitrust Litig.*, 221 F.R.D. 260, 277 (D. Mass. 2004). Because Plaintiff was, at all relevant times, a resident of Florida and the sale and use of SERI® occurred outside of Massachusetts, her claims are beyond the purview of Mass. Gen. Laws Ch. 93A and fail as a matter of law.

CONCLUSION

WHEREFORE, for the foregoing reasons, and for the reasons set forth in Sofregen's motion, Sofregen respectfully requests that this Court grant its motion, and dismiss all claims asserted against it in their entirety with prejudice.

Respectfully submitted,

SOFREGEN MEDICAL, INC.,

By its Attorneys,

/s/ Ellen Epstein Cohen
Ellen Epstein Cohen (BBO# 543136)
ecohen@adlercohen.com
Ian Keefe (BBO# 680156)
ikeefe@adlercohen.com
Shea A. Miller (BBO# 699326)
smiller@adlercohen.com
Adler | Cohen | Harvey | Wakeman | Guekguezian, LLP
75 Federal Street, 10th Floor
Boston, MA 02110
(617) 423-6674

Dated: January 31, 2019

CERTIFICATE OF SERVICE

I hereby certify that above document was filed through ECF system and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on January 31, 2019.

/s/ Shea A. Miller______________________________
Shea A. Miller